DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Refer to: CFN/FEI 1176209

HFI-35

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

M5225A

01-BLT-12

January 18, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph Rosen, President
Sera-Tec Biologicals Limited Partnership
223 N. Center Drive
North Brunswick, New Jersey 08902

Dear Mr. Rosen:

During a Food and Drug Administration (FDA) inspection of your plasma center located at 117 Third Street, Richmond, Virginia, on November 29 through December 19, 2000, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680, as follows:

1. Failure to maintain and/or follow adequate written standard operating procedures (SOP) including all steps to be followed in the collection, processing, storage, and distribution of blood and blood products [21 CFR 606.100(b)], in that:

   a. The lookback department of Sera-Tec, North Brunswick, New Jersey, was not notified, in accordance with established procedures, within one day of the positive test results of 30 prior donations from donor [redacted] who tested repeatedly reactive for anti-HCV on September 27, 2000. The Quality Assurance staff documented that the consignee of 21of the 30 units of Source Plasma was notified on October 7, 2000 when, in fact, the notification letter was not issued until December 4, 2000 during the FDA inspection.

   b. Donor #[redacted], who tested repeatedly reactive, confirmed positive for anti-HIV-1/2 in July 1998, was not notified of the positive test result within one day of receipt of results in accordance with the SOP titled, "Unacceptable Donor/Unit Management Section 820." In addition, the local health department was not notified of the positive test result of donor #[redacted], as required by established procedures.

   c. Your firm failed to follow the SOP titled, "Unacceptable Donor/Unit Management," in that the packing list associated with ten units of Source Plasma which tested repeatedly reactive for anti-HIV-1/2, contained an incorrect statement

identifying the units as "negative for anti-HIV." These units were distributed on March 10, 1999.

d. Numerous defective lots of soft goods and plasma containers were not labeled and segregated in accordance with the SOP titled, "Soft Goods, Section 210."

2. Failure to maintain and/or follow adequate procedures for conducting a thorough investigation, including the conclusions and follow-up, of any unexplained discrepancy or the failure of a lot or unit to meet any of its specifications [21 CFR 606.100(c)].

a. Your firm failed to quarantine defective lots of [redacted] soft goods and plasma containers until a thorough investigation was completed. Instead, Sera-Tec continued to use the defective lots for the collection of Source Plasma.

b. Your firm failed to conduct an investigation to determine whether the defective soft goods and plasma containers were associated with donor adverse reactions.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. The specific violations noted in this letter and in the FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. Such actions include, but are not limited to, license suspension and/or revocation, seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,

Lee Bowers
Director, Baltimore District

cc: Mr. Edward Bell, Manager
Sera-Tec Biologicals Limited Partnership
117 Third Street
Richmond, Virginia 23219